Shenzhen Dazhou Medical Technology Co., Ltd.
% Mandy Li
Regulatory Affair
Cosmos Biomed Consulting Co., Ltd.
Room 1201, No.1, 188 Alley, Shuangliu Road
Changning District
Shanghai City,
CHINA

February 21, 2025

Re: K241186
Trade/Device Name: Synthetic Bone Graft Particulate
Regulation Number: 21 CFR 872.3930
Regulation Name: Bone Grafting Material
Regulatory Class: Class II
Product Code: LYC
Dated: April 26, 2024
Received: January 21, 2025

Dear Mandy Li:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device" (https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Sherrill Lathrop Blitzer

for Andrew Steen
Assistant Director
DHT1B: Division of Dental and
ENT Devices
OHT1: Office of Ophthalmic, Anesthesia,
Respiratory, ENT, and Dental Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K241186

Device Name
Synthetic Bone Graft Particulate

Indications for Use *(Describe)*
Synthetic Bone Graft Particulate is intended to be used to augment the alveolar bone in tooth extraction procedures. (i.e., use in extraction sockets only)

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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510(k) SUMMARY

1. Submission Information

Submitter: Shenzhen Dazhou Medical Technology Co., Ltd.
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Date of preparation: February 21, 2025

2. Device Name and Classification

Product Name:	Synthetic Bone Graft Particulate
Classification Name:	Bone Grafting Material, Synthetic
Common or Usual Name:	Bone grafting material
Regulation Number:	21 CFR 872.3930
Product Code:	LYC

3. Predicate Device(s)

Product Name:	PerioGlas - Bioglass Bone Graft Particulate (K040278)
Common or Usual Name:	Bone grafting material
Regulation Number:	21 CFR 872.3930
Product Code:	LYC

4. Device Description

Synthetic Bone Graft Particulate is a synthetic absorbable osteoconductive bone graft substitute manufactured from 45S5 bioactive glass. The device is in particulate form with a size range of 0.5 mm to 1 mm.

The device is intended for augmenting alveolar bone in tooth extraction procedures. At time of use, the device is mixed with sterile saline to form a wet sandy paste that is applied to the defect. Synthetic Bone Graft Particulate is progressively resorbed and replaced by new bone tissue during the healing process.

It is supplied sterile, packaged in a rubber stopper-sealed glass bottle within a sterile barrier

package (Tyvek-sealed PETG box). The device packages are protected by carboard box.

5. Indications for Use

Synthetic Bone Graft Particulate is intended to be used to augment the alveolar bone in tooth extraction procedures. (i.e., use in extraction sockets only)

6. Comparison to the Predicate Device

Substantial Equivalence Comparison	**Predicate Device** [K040278] PerioGlas -Bioglass Synthetic Bone Graft Particulate	**Proposed Device** Synthetic Bone Graft Particulate
Classification & Product Code	Class II, LYC	Same as predicate
Indications for Use	PerioGlas – Bioglass Bone Graft Particulate is indicated to be packed into bony voids or gaps to fill and/or augment oral, dental intraosseous, and craniofacial defects. These defects may include: periodontal/infrabony defects; alveolar ridge augmentation (sinusotomy, osteotomy, cystectomy); dental extraction sites (ridge maintenance, implant preparation/placement); sinus lifts; cystic defects; craniofacial augmentation. PerioGlas may be used alone in a manner comparable to autogenous bone graft chips or allograft bone particulate (demineralized freeze dried bone), or it may be mixed with either as a bone graft extender.	Synthetic Bone Graft Particulate is intended to be used to augment the alveolar bone in tooth extraction procedures. (i.e., use in extraction sockets only)
Application	Gently packed into defect sites as non-structural scaffold for body's natural	Same as predicate

Substantial Equivalence Comparison	**Predicate Device** [K040278] PerioGlas -Bioglass Synthetic Bone Graft Particulate	**Proposed Device** Synthetic Bone Graft Particulate
	healing and bone regeneration processes	
Material	Bioactive glass	Same as predicate
Morphology	Irregular dense particulate	Same as predicate
Particle Size	90-710 microns	500-1000 microns
Resorption Rate	Majority absorbed by six months	Same as predicate
Mechanical	Particulate material; not intended for use in load-bearing defects without proper internal or external fixation	Particulate material; requires an adequate healing period prior to load-bearing
Performance	Bone infiltration occurs throughout the grafts site via osteoconduction, resulting in increased graft site mechanical stiffness and strength	Bone infiltration occurs throughout the grafts site
Bone Remodeling	New bone grows into the graft area via osteoconduction. The material is slowly absorbed and replaced by the host bone.	Same as predicate

Synthetic Bone Graft Particulate can be used in the same intended way as PerioGlas, without bone extender materials, and it thus substantially equivalent to PerioGlas for the same indication for use.

The technological characteristics of Synthetic Bone Graft Particulate are similar to the predicate in terms of the device material. Both devices are calcium phospho-silicate inorganic materials. The particle size of Synthetic Bone Graft Particulate is similar to that of PerioGlas. Synthetic Bone Graft Particulate and the predicate are designed to be gently packed into defect sites, functioning as a non-structural scaffold for the body's natural healing and bone regeneration process. The device acts as a synthetic, inorganic, biocompatible and osteoconductive scaffold into which new bone will grow.

7. Performance Data

Non-clinical tests were performed on the proposed device.

Sterilization complies with ISO 11137. Product shelf-life testing was evaluated to ensure the labeled shelf life. Assessment of biocompatibility was completed per ISO 10993-1. The evaluation included cytotoxicity per ISO 10993-5, sensitization per ISO 10993-10, irritation per ISO 10993-23, pyrogenicity per USP<151> and ISO 10993-11, acute systemic toxicity per ISO 10993-11, subchronic systemic toxicity per ISO 10993-11 and ISO 10993-6, implantation per ISO 10993-6, and genotoxicity per ISO 10993-3. Chemical composition and crystallinity testing were completed per ASTM F1538-03. Morphology testing was completed per ISO 9276-6. Particle size distribution testing was completed per USP<786>. pH value testing was completed per USP<791>. Bioactivity testing was completed per ISO 23317. Water solubility testing was completed per OECD Test No. 105. The FT-IR method was utilized to analyze the additive residue. Bacterial endotoxin testing was performed using the LAL test method, following the USP <85> Bacterial Endotoxins Test, and met the limits (<20 EU/device).

Animal Study

Pre-clinical study was conducted in a canine dental defect model to evaluate the in vivo absorbability and bone healing/regeneration ability. The study was comparative between the subject and predicate devices. General observations, hematology tests, gross pathological examinations, micro-CT scans, and histological evaluations (H&E Staining and Masson-Goldner Staining) were performed at 4, 12, and 26 weeks post-operation.

8. Conclusion

The test results indicate that Synthetic Bone Graft Particulate is substantial equivalence to the predicate device PerioGlas- Bioglass Bone Graft Particulate.